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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,444	09/11/2003	Andrzej Chanduszeko	NMT-015	4893

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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/660,444

Applicant(s)

CHANDUSZKO ET AL.

Examiner

M. Thomas Andersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31, 34-42 and 60-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31, 34-42 and 60-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/01/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of the response filed 11/01/2006, to the non-final Office action dated 8/01/2006.

Specification

Acknowledgement is made to the amendment of the specification. The objection to the specification is thus withdrawn.

Response to Amendments

Applicant's amendments filed 11/01/2006 have been fully considered. New rejections in view of the amendments are outlined below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 34-35, 60-63 are rejected under 35 U.S.C. 102(a) as being anticipated by Ginn, U.S. 6,702,835.

Ginn discloses a needle apparatus for closing septal defects and methods for using such apparatus. Particularly, Ginn discloses introducing into a heart of a patient a delivery member having a first flexible member 54 having a first end and a second free end portion (distal end of 54); introducing the second free end portion through a patent foramen ovale (figure 5B); contacting the second free end portion with a left atrial side

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of a septum primum (figure 5B – the distal end of 54 contacts the left atrial side of the septum primum); puncturing a hold through the septum primum (cf. figures 5A, 5B); withdrawing the second free end portion of the flexible member from the left atrial side (cf. figures 5C, 5D); and introducing an occlusion device 14 (a septal occluder) for occluding the patent foramen ovale through the hold in the septum primum. Ginn further discloses the step of introducing an apparatus 40 for joining tissue (figure 5D).

Ginn's method comprises the step of placing the first end portion of the first flexible member 54 on a right atrial side of the septum primum.

Ginn's delivery member further comprises a second flexible member 30, said second flexible member having a first end portion and a second free end portion (free from the first member 54), and wherein the second free end portion of the second flexible member contacts the left atrial side of the septum primum (figure 5D). Further, the first end of the second flexible member is placed on a right side of the septum primum (figure 5C).

Ginn discloses another embodiment where the flexible member can be considered spiral shaped or a coil. See figure 6; col. 10, lines 41-52.

Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Das, U.S. 5,334,217. Das discloses a septal defect closure device and related method.

Das discloses the method of introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members (figures 5C, 8); introducing said hexagonally shaped flexible members through a patent forament ovale (figure 8); placing at least one of the hexagonally shaped flexible members on a

left atrial side of a septum primum (figure 10); and withdrawing the at least one hexagonally shaped flexible member from the left atrial side (withdrawing one of the hexagonally shaped flexible members is considered to be shown in figure 8 as one of the members advance through the PFO).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das, as applied to claim 37 above, in view of Ginn. Das does not explicitly show puncturing a hole through the septum primum. However, Ginn shows that sometimes the tissue of the septum primum overlaps forming more of a channel rather than a hole. In such a case, it would have been obvious to one having ordinary skill in the art at the time of the invention to form a hole in the septum primum in order to deliver the septal defect closure device disclosed by Das. In such a case, the closure device would travel through the formed hole (rather than the natural hole disclosed by Das) to the other side and there expand, thus occluding the PFO.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginn, as applied to claim 31 above, in view of Sawyer, U.S. 5,749,895. Ginn does not expressly disclose a tissue welding apparatus. However, use of a tissue welding apparatus is well-known in the art, as evidenced by Sawyer. It would have been obvious to use a

tissue welding apparatus in addition to a septal defect occluder in order to better occlude the PFO defect.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das, as applied to claim 37 above, in view of Ginn, and further in view of Sawyer. Neither Das nor Ginn expressly disclose a tissue welding apparatus. However, as mentioned above, use of a tissue welding apparatus is well-known in the art, as evidenced by Sawyer. It would have been obvious to use a tissue welding apparatus in addition to a septal defect occluder, as disclosed by Das, in order to better occlude the PFO defect.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

January 16, 2007

A handwritten signature in black ink, appearing to read "M J Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER